



AUG 12 2008

K081942

US

Vygon Inc, LLC, 2495 General Armistead Avenue, Norristown, PA 19403, USA  
Office Phone: 610 539-9300 850462-2582 Office Fax: 610 539-8333

**PREMARKET NOTIFICATION  
510(k) SUMMARY  
(As Required By 21 CFR 807.93)**

**Date of Preparation: June 20, 2008**

**Applicant:** Vygon Neuro  
2495 General Armistead Ave.  
Norristown, PA 19403

**Contact Individual:** Courtney Smith, Regulatory Affairs Manager  
610-539-9300 Ext. 110

**Trade Name:** Neurocath Ag

**Common Name:** External Drainage Catheter

**Regulation Number:** 882.5550

**Product Code:** JXG

**Classification Name:** Shunt, Central Nervous System and Components

**Classification:** Class II

**Predicate Device Name:** Fifth Ventricle External Drainage Catheter (K800168/ K870660),  
Extracorporeal Ventricular Catheters (preamendment)

**Device Description:** The Neurocath Ag is an external drainage catheter composed of polyurethane and impregnated with the silver ions for the purpose of radiopacity.  
The catheter is available with 3 holes off-set at 120°, or 16 holes, in lengths of 32, 23.5, and 15.5cm. Biocompatibility and performance testing demonstrates the safety and efficacy of these devices.  
The Neurocath Ag is supplied with a stainless steel stylet (for introducing it into the ventricle), a stainless steel subgaleal trochar (for tunneled catheter placement), a male luer connector, a slitted wing and a compression hub (for connecting the catheter to the tubing set). The Neurocath Ag catheter is available individually or packaged with the tubing set.

The Neurocath Ag catheters are as follows:

| Description            | Reference |
|------------------------|-----------|
| Neurocath Ag Catheters | 8335.xxx  |

**Intended Use:** The Neurocath Ag catheter is designed to be temporarily implanted (less than 30 days) for the drainage of cerebrospinal fluid (CSF) to reduce and control increased intracranial pressure (ICP).

**Technology Characteristics:** The fundamental scientific technology of the Neurocath Ag is substantially equivalent to the predicate devices.

**Summary of Design Control Activities:**

Biocompatibility testing of the material demonstrate that it is non-irritant and non-toxic. Performance testing demonstrates that the changes do not affect safety or efficacy. Risk Assessment was conducted in compliance with ISO 14971.

**Conclusion:**

The only change between the predicate device (Fifth Ventricle Drainage Catheter K800168 and K853365) and the preamendment predicate device and the Neurocath Ag is the change in material from barium impregnated silicone and silver impregnated silicone, respectively, to polyurethane impregnated with silver ions. Biocompatibility testing, performance testing and risk assessment demonstrate that the Neurocath Ag is safe and effective to use, when used in accordance with the supplied instructions for use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Vygon Neuro  
% Courtney Smith  
Regulatory Affairs Manager  
2495 General Armistead Avenue  
Norristown, Pennsylvania 19403

**AUG 12 2008**

Re: K081942

Trade/Device Name: Neurocath Ag  
Regulation Number: 21 CFR 882.5550  
Regulation Name: Central nervous system fluid shunt and components  
Regulatory Class: II  
Product Code: JXG  
Dated: July 7, 2008  
Received: July 16, 2008

Dear Courtney Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K081942

Device Name: Neurocath Ag

#### Indications For Use:

The Neurocath Ag catheter is designed to be temporarily implanted (less than 30 days) for the drainage of cerebrospinal fluid (CSF) to reduce and control increased intracranial pressure (ICP).


Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

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